UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

R.S.B., a minor, by and through his Parent and Next Friend, Stephanie Hammar, and STEPHANIE HAMMAR, Individually,

Plaintiffs,

v.

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,

Defendants.

Case No. 20-CV-01402-WCG

JOINT RULE 26(f) REPORT

R.S.B., a minor, and Stephanie Hammar ("Plaintiffs") and Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively, "Merck"), by and through their undersigned counsel, submit this Joint Rule 26(f) Report.

1. Statement of Conference.

Pursuant to Federal Rule of Civil Procedure 26(f) and the Court's December 11, 2020 Order (ECF No. 21), counsel for the parties telephonically conferred on December 18 and December 22, 2020, regarding the matters set forth in Federal Rule of Civil Procedure 26. Present on behalf of Plaintiffs was Attorney Kimberly Beck of Beck Law Center. Stephen Marshall of Venable LLP participated for Merck along with Allen C. Schlinsog, Jr. of Reinhart Boerner Van Deuren s.c.

The parties' Rule 16(b) scheduling conference with the Court will be held telephonically on January 4, 2021, at 9:30 a.m.

2. Nature and Basis of the Claims and Defenses.

Plaintiffs allege that R.S.B. suffered neuropsychiatric injuries from montelukast sodium, a medication indicated to prevent and treat asthma, as well as to treat symptoms of allergic rhinitis. Plaintiffs allege that R.S.B. took montelukast sodium in the form of Merck's branded product, Singulair®, from approximately December 2010 to August 2012, and then from August 2012 and into 2014 used generic montelukast that was neither manufactured nor distributed by Merck. Plaintiffs assert claims for strict products liability–design defect (Count I), strict products liability–failure to warn (Count II), negligence (Count III), breach of express warranty (Count IV), and breach of implied warranties (Count V).

Two threshold legal questions frame this dispute and are potentially dispositive. The first question arises from Plaintiffs' allegations that R.S.B.'s symptoms continued and worsened after 2012. One of Plaintiffs' theories is that R.S.B.'s injuries worsened as a result of his use of generic montelukast that Merck neither manufactured, distributed nor sold. Plaintiffs assert, in support of their position, that Merck as the company that filed the New Drug Application for Singulair® had a duty to adequately warn of neuropsychiatric side effects, and that Merck is liable for injuries arising from a breach of that duty, regardless of whether Minor Plaintiff was using brand Singulair® or generic montelukast at the time of the injury (i.e., whether Wisconsin recognizes "innovator liability"). The legal issue, therefore, is whether Merck can be liable under Wisconsin law for injuries caused by generic montelukast.

The answer to that threshold question determines two important points. First, it establishes the time-frame for assessing Merck's duty to warn, i.e., is Merck's duty to warn evaluated as of August 2012 when R.S.B. stopped using Singulair® or does Merck's duty continue even though R.S.B. was not using Merck's medicine. Additionally, the answer to that question is material to

establishing what if any injuries can be attributed to Merck, i.e. are the potentially compensable injuries limited to those caused by R.S.B.'s Singulair® use up until August 2012 or is Merck also liable for R.S.B.'s injuries from generic montelukast. The question is purely legal, essential, and can be addressed preliminarily with limited discovery.

The second threshold question involves whether Plaintiffs' failure to warn claims are preempted as a matter of federal law. *See e.g. Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). It is Merck's position, which Plaintiffs deny, that there is clear evidence that the FDA would not have allowed any material change to the Warnings and Precautions concerning neuropsychiatric events that were already in place in the Prescribing Information for Singulair® during the time-frame relevant to this case. The answer to this legal question is also essential, potentially dispositive, and should require discovery less than what may otherwise be required. The parties agree that dedicating the first two phases of the case to resolving these issues would be the most efficient means of moving forward and suggest that the Court stay any further deadlines and unrelated discovery until those phases are completed.

3. State of the Pleadings.

Merck has moved to dismiss Counts I, IV and V of Plaintiffs' complaint. That motion is fully briefed. Plaintiffs have recently stated that they wish to file an Amended Complaint, and offered to do so on or before December 31, 2020. Merck has no objection to Plaintiffs filing an Amended Complaint, but requests 30 days from service of any Amended Complaint to file any responsive pleading. Plaintiffs have no objection to that request.

4. Possibility of Prompt Resolution or Settlement.

The parties do not believe settlement is likely at this stage of the case.

5. Preservation of Discoverable Information.

The parties each state that they have taken appropriate steps to preserve discoverable information, including electronically stored information, and will continue to make necessary and reasonable efforts to preserve discoverable information, including electronically stored information.

6. Phased Approach to Discovery and Summary Judgment.

a. Phase One – "Innovator Liability".

A threshold issue in this case is whether Merck, the brand manufacturer of Singulair® and the party that filed and held the New Drug Applications, can be liable for injuries caused by generic montelukast sodium manufactured, distributed, and sold by one or more non-Merck entities. Resolving that question will define the extent of Plaintiffs' claims, because, as noted above, it will determine when Merck's duty ceased as to these Plaintiffs.

The parties believe this issue is appropriate for the Court's Fast Track Summary Judgment Procedure. Only limited discovery from Plaintiffs will be needed to determine the frequency, dosage and dates of R.S.B.'s ingestion of branded Singulair® and generic montelukast sodium, as well as the onset and extent of his alleged injuries.

Plaintiffs have asked that they be given until April 1, 2021 to produce the medical records related to this issue. The parties suggest the following deadlines for their Fast Track Summary Judgment submissions: Merck's motion and supporting documents would be filed on or before April 23, 2021; Plaintiffs' response would be due on May 14, 2021; and Merck's Reply would be due on June 4, 2021. The parties agree that by setting this schedule, Plaintiffs will not be prejudiced from seeking leave to file a sur-reply if otherwise appropriate.

b. Phase Two – Preemption.

Once the innovator liability question is resolved, which will set the relevant timeframe for the Court to evaluate the federal preemption issue, the parties propose that the next phase of the case be limited to the issue of whether Plaintiffs' failure to warn claims are preempted. This issue has the potential to resolve the Plaintiffs' failure to warn claims. It is Merck's position that there is clear evidence that the FDA was fully informed about the material information concerning the risks alleged and would not have allowed any relevant change to the Warnings and Precautions that were already in place, such that Plaintiffs' state law failure to warn claims are preempted by federal law. Plaintiffs deny that Merck's position is supported by the law or the evidence.

The parties agree that this issue also is appropriate for the Court's Fast Track Summary Judgment Procedure. They agree that Plaintiffs will be entitled to discovery of certain aspects of Merck's regulatory files. Given the lengthy regulatory history for Singulair® and the resulting volume of materials, the parties anticipate that it will take Merck 8-10 months to produce that information. To the extent reasonable, Merck will produce the regulatory file on a rolling basis.

Accordingly, the parties suggest the following deadlines for Phase Two: fact discovery related to preemption, including the production of pertinent portions of Merck's regulatory file, and any reasonably necessary depositions, shall be completed by November 4, 2021; Merck's motion for summary judgment and supporting documents would be filed on December 4, 2021; Plaintiffs' response would be due on January 16, 2022; and Merck's Reply would be due on January 30, 2022. The parties agree that by setting this schedule Plaintiffs will not be prejudiced from seeking leave to file a sur-reply if otherwise appropriate.

7. Other Discovery Issues.

a. Commencement of Discovery.

The parties agree that discovery can commence immediately as outlined above, but all other discovery will be stayed.

b. Rule 26(a) Initial Disclosures.

The parties will provide Initial Disclosures by January 15, 2021.

c. Discovery of Electronically Stored Information.

At this time, the parties do not anticipate any special issues with regard to the disclosure or discovery of electronically stored information, but will promptly address any issues that arise during the course of discovery.

d. Claims of Privilege or Protection as Trial Preparation Materials.

The parties do not anticipate any special issues with regard to the disclosure or discovery of privileged or work product information. The parties agree that if a responding party believes that any requested information and/or documents are privileged, that party will state as much in its response(s) and provide a privilege log. The parties agree that communications with experts and drafts of expert reports will not be discoverable.

e. Limitations on Discovery Imposed Under Federal or Local Rules.

The parties agree that the timing, extent, and limitations on discovery shall be those set forth in the Federal Rules of Civil Procedure and the Court's Local Rules, as modified by the staging of discovery set forth herein. All parties reserve the right to move for additional depositions and/or interrogatories pursuant to Federal Rules of Civil Procedure 30(a) and 33(a), if necessary.

f. Other Orders to be Entered under Rule 26(c) or Rules 16(b) and (c).

i. Amendment of Pleadings.

Plaintiff wishes to file an Amended Complaint. The parties do not currently anticipate the need to make any other amendments to the pleadings, but, nonetheless agree that any amendments to the pleadings shall be made by February 8, 2021, unless the Court orders otherwise.

ii. Time to Join Other Parties.

The parties do not currently anticipate the need to join any additional parties, but, nonetheless agree that all additional parties shall be joined by February 8, 2021, unless the Court orders otherwise.

8. Length of Trial.

The parties anticipate trial in this matter will take 12 trial days.

9. Jury Trial.

A jury trial has been requested in this matter.

We look forward to discussing this with you on January 4, 2021.

Dated: December 28, 2020

Respectfully submitted,

/s/ Allen C. Schlinsog, Jr.

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